CORPORATE INTEGRITY AGREEMENT

BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE

DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND

VILLAVIEW COMMUNITY HOSPITAL, INC.

I. PREAMBLE

VillaView Community Hospital, Inc. ("VillaView") hereby enters into this Corporate Integrity Agreement ("CIA") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") to ensure compliance with the requirements of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f))(hereinafter collectively referred to as the "Federal health care programs"), by its physicians, employees, and other health care professionals, as well as all third parties with whom VillaView may choose to engage to act as billing, contracting, or marketing agents or consultants for VillaView. VillaView's compliance with the terms and conditions in this CIA shall constitute an element of VillaView's present responsibility with regard to participation in the Federal health care programs. Contemporaneously with this CIA, VillaView is entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement.

II. TERM OF THE CIA

The period of the compliance obligations assumed by VillaView under this CIA shall be three (3) years from the effective date of this CIA (unless otherwise specified). The effective date of this CIA will be the date on which the final signatory of this CIA executes this CIA (the "effective date").

III. CORPORATE INTEGRITY OBLIGATIONS

VillaView shall establish a compliance program that includes the following elements.

A. Compliance Officer.

Within ninety (90) days after the effective date of this CIA, VillaView shall appoint an individual to serve as Compliance Officer, who shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with the requirements of the Federal health care programs. The Compliance Officer shall be a member of senior management of VillaView, shall make regular (at least quarterly) reports regarding compliance matters directly to the CEO and/or to the Board of Directors of VillaView and shall be authorized to report to the Board of Directors at any time. The Compliance Officer shall be responsible for monitoring the day-to-day activities engaged in by VillaView to further its compliance objectives as well as any reporting obligations created under this CIA. In the event a new Compliance Officer is appointed during the term of this CIA, VillaView shall notify the OIG, in writing, within fifteen (15) days of such a change.

VillaView shall also appoint a Compliance Committee within ninety (90) days after the effective date of this CIA. The Compliance Committee shall, at a minimum, include the Compliance Officer and any other appropriate officers as necessary to meet the requirements of this CIA within the provider's corporate structure (e.g., senior executives of each major department, such as billing, clinical, human resources, audit, and operations). The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities.

B. Written Standards.

- 1. Code of Conduct. VillaView shall establish and distribute a Code of Conduct. The Code of Conduct shall be distributed to all employees, contractors, and agents within ninety (90) days of the effective date of this CIA. VillaView shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of managers, supervisors, and all other employees. The Code of Conduct shall, at a minimum, set forth:
 - a. VillaView's commitment to full compliance with all statutes, regulations, and guidelines applicable to Federal health care

programs, including its commitment to prepare and submit accurate billings consistent with Federal health care program regulations and procedures or instructions otherwise communicated by the Health Care Financing Administration ("HCFA") (or other appropriate regulatory agencies) and/or its agents;

- b. VillaView's requirement that all of its employees, contractors, and agents shall be expected to comply with all statutes, regulations, and guidelines applicable to Federal health care programs and with VillaView's own policies and procedures (including the requirements of this CIA);
- c. the requirement that all of VillaView's employees, contractors, and agents shall be expected to report suspected violations of any statute, regulation, or guideline applicable to Federal health care programs or with VillaView's own policies and procedures to management or through the Confidential Disclosure Program;
- d. the possible consequences to both VillaView and to any employee, contractor, or agent of failure to comply with all statutes, regulations, and guidelines applicable to Federal health care programs and with VillaView's own policies and procedures, or of failure to report such non-compliance; and
- e. the right of all employees, contractors, and agents to use the Confidential Disclosure Program, as well as VillaView's commitment to confidentiality and non-retaliation with respect to disclosures.

Within one hundred and twenty (120) days of the effective date of the CIA, each employee, contractor, and agent shall certify, in writing, that he or she has received, read, understands, and will abide by VillaView's Code of Conduct. New employees, contractors, and agents shall receive the Code of Conduct and shall complete the required certification within two (2) weeks after the commencement of their employment or contract or within one hundred and twenty (120) days of the effective date of the CIA, whichever is later.

VillaView will annually review the Code of Conduct and will make any necessary revisions. These revisions shall be distributed within thirty (30) days of initiating such a

change. Employees, contractors, and agents shall certify on an annual basis that they have received, read, understand and will abide by the Code of Conduct.

2. Policies and Procedures. Within ninety (90) days of the effective date of this CIA, VillaView shall develop and initiate implementation of written Policies and Procedures regarding the operation of VillaView's compliance program and its compliance with all Federal and state health care statutes, regulations, and guidelines, including the requirements of the Federal health care programs. At a minimum, the Policies and Procedures shall specifically address the prohibitions contained in 42 U.S.C. § 1320a-7b(b) (the "anti-kickback" statute) and 42 U.S.C. § 1395nn (the "Stark" statute). VillaView shall institute procedures requiring legal review of all contracts and agreements that are entered into with individuals or entities who are either directly or indirectly in a position to refer patients to VillaView. In addition, the Policies and Procedures shall include disciplinary guidelines and methods for employees to make disclosures or otherwise report on compliance issues to VillaView management through the Confidential Disclosure Program required by section III.E. VillaView shall assess and update as necessary the Policies and Procedures at least annually and more frequently, as appropriate. A summary of the Policies and Procedures will be provided to OIG in the Implementation Report. The Policies and Procedures will be available to OIG upon request.

Within one hundred and twenty (120) days of the effective date of the CIA, the relevant portions of the Policies and Procedures shall be distributed to all appropriate employees, contractors, and agents. Compliance staff or supervisors should be available to explain any and all policies and procedures.

C. Training and Education.

Within one hundred and twenty (120) days of the effective date of this CIA, VillaView shall provide at least two (2) hours of training to each employee, contractor, and agent. This training shall explain VillaView's:

- 1. Corporate Integrity Agreement requirements;
- 2. Compliance Program (including the Policies and Procedures as they pertain to general compliance issues);
- 3. Code of Conduct;

- 4. An introduction to the False Claims Act (31 U.S.C. §§ 3729-3733) and the Civil Monetary Penalties Law (42 U.S.C. § 1320a-7a); and
- 5. The specific policies and procedures relating to the anti-kickback and Stark statutes, including the need for legal review.

These training material shall be made available to the OIG, upon request. Persons providing the training must be knowledgeable in all necessary subjects as specified above.

New employees shall receive the general training described above within thirty (30) days of the beginning of their employment or within one hundred and twenty (120) days after the effective date of this CIA, whichever is later. Each year, every employee, contractor, and agent shall receive such general training on an annual basis. Alternatively, VillaView may issue, annually, a comprehensive study guide with comprehension reviews reiterating the applicable policies and procedures and provide a forum (with choices for different times and dates to allow for different shifts) for individuals to ask questions of people qualified to provide answers.

Each employee, contractor, and agent shall certify, in writing, that he or she has attended the required training or completed the study guide and comprehension review. The certification shall specify the type of training received and the date received. The Compliance Officer shall retain the certifications, along with specific course materials, including any comprehension reviews. These shall be made available to OIG upon request.

D. Review Procedures.

VillaView shall retain an entity, such as an accounting, auditing or law firm (hereinafter "Independent Review Organization"), to perform review procedures to assist VillaView in assessing the adequacy of its contracting and compliance practices pursuant to this CIA. This shall be an annual requirement and shall cover a twelve (12) month period. The Independent Review Organization must have expertise in the requirements of the Federal health care programs that prohibit certain investment, compensation, and referral arrangements, such as the anti-kickback and Stark statutes. The Independent Review Organization must be retained to conduct the audit of the first year within ninety (90) days of the effective date of this CIA.

The Independent Review Organization will conduct two separate engagements. One will be an analysis of VillaView's contracting practices to assist VillaView and OIG in determining compliance with all applicable statutes, regulations, and directives/guidance ("contracting engagement"). The second engagement will determine whether VillaView is in compliance with this CIA ("compliance engagement").

- 1. Contracting Engagement. The contracting engagement shall consist of a review of all contracts and agreements, appended hereto as Exhibit 1,¹ except those that are designated as "Community/Educational Agreements" and those "Purchase/ Service Agreements" that are marked with an asterisk. Once a contract or agreement has been reviewed, subsequent review will only be required if there are any amendments thereto. Any new contracts or agreements shall be reviewed. Each review shall include an analysis of whether the contract or agreement is in compliance with the anti-kickback and Stark statutes. The Independent Review Organization shall also conduct an analysis of the steps VillaView is taking to bring its operations into compliance or to correct problems identified by the Independent Review Organization.
- 2. Compliance Engagement. An Independent Review Organization shall also conduct a compliance engagement, that shall provide an analysis of whether VillaView's program, policies, procedures, and operations comply with the terms of this CIA. This engagement shall include a section by section analysis of the requirements of this CIA.

A complete copy of the Independent Review Organization's contracting and compliance engagement shall be included in each of VillaView's Annual Reports to OIG.

3. Verification/Validation. In the event that the OIG determines that it is necessary to conduct an independent review to determine whether VillaView has substantially performed the review procedures, VillaView agrees to pay for the reasonable cost of any such review or engagement by the OIG or any of its designated agents.

E. Confidential Disclosure Program.

Within ninety (90) days after the effective date of this CIA, VillaView shall establish a Confidential Disclosure Program, which must include measures (e.g., a toll-

¹Exhibit 1 represents all contracts and agreements with VillaView at the time it signed this CIA.

free compliance telephone line) to enable employees, contractors, agents, or other individuals to disclose any identified issues or questions associated with VillaView's policies, practices or procedures with respect to the Federal health care program, believed by the individual to be inappropriate. The Confidential Disclosure Program shall allow for such disclosure to be made to the Compliance Officer or some other person who is not in the reporting individual's chain of command. VillaView shall publicize the existence of the program (e.g., e-mail to employees or post hotline number or other access in prominent common areas).

The Confidential Disclosure Program shall emphasize a non-retribution, non-retaliation policy, and shall include a reporting mechanism for anonymous, confidential communication. Upon receipt of a complaint, the Compliance Officer (or designee) shall gather the information in such a way as to elicit all relevant information, and, if possible, from the individual reporting the alleged misconduct. The Compliance Officer (or designee) shall make a preliminary good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, VillaView shall conduct an internal review of the allegations set forth in such a disclosure and ensure that proper follow-up is conducted.

The Compliance Officer shall maintain a confidential disclosure log, which shall include a record and summary of each allegation received, the status of the respective investigations, and any corrective action taken in response to the investigation.

F. Ineligible Persons.

VillaView shall not employ, engage as contractors, or grant staff privileges to any "Ineligible Person." For purposes of this CIA, an "Ineligible Person" shall be any individual or entity who: (i) is currently excluded, suspended, debarred or otherwise ineligible to participate in the Federal health care programs; or (ii) has been convicted of a criminal offense related to the provision of health care items or services and has not been reinstated in the Federal health care programs after a period of exclusion, suspension, debarment, or ineligibility.

Within one hundred and twenty (120) days of the effective date of this CIA, VillaView will review its list of current employees and contractors against the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://www.arnet.gov/epls) and the HHS/OIG Cumulative Sanction

Report (available through the Internet at http://www.dhhs.gov/progorg/oig) to ensure that it is not currently employing or contracting with any Ineligible Person. Thereafter, VillaView will review the list annually to ensure that no current employees or contractors are or have become Ineligible Persons.

To prevent hiring or contracting with any Ineligible Person, VillaView shall screen all prospective employees and prospective contractors prior to engaging their services by (i) requiring applicants to disclose whether they are Ineligible Persons; and (ii) reviewing the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://www.arnet.gov/epls) and the HHS/OIG Cumulative Sanction Report (available through the Internet at http://www.dhhs.gov/progorg/oig).

If VillaView has information that an employee or agent is an Ineligible Person, charged with a criminal offense related to any Federal health care program, or is suspended or proposed for exclusion during his or her employment or contract with VillaView, within five (5) days of receiving such information VillaView will remove such employee from responsibility for, or involvement with, VillaView's operations related to the Federal health care programs until the resolution of such criminal action, suspension, or proposed exclusion. If VillaView continues to contract with or employ an Ineligible Person, then VillaView must ensure that the cost of that individual is not included in any cost report or claim to Federal health care programs and that individual is not providing care to beneficiaries or recipients of Federal health care programs.

G. Notification of Proceedings.

Within thirty (30) days of discovery, VillaView shall notify OIG, in writing, of any ongoing investigation or legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that VillaView, its employees, or agents have committed a crime or have engaged in fraudulent activities or any other knowing misconduct. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. VillaView shall also provide written notice to OIG within thirty (30) days of the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings, if any.

H. Reporting.

If, at any time, VillaView identifies any billing, coding or other policies, procedures and/or practices that result in an overpayment, VillaView shall notify the

payor (e.g., Medicare fiscal intermediary or Medi-Cal) within thirty (30) days of discovering the deficiency or overpayment and take remedial steps within sixty (60) days of discovery (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the deficiency or overpayment from recurring. The notice to the payor shall include:

- 1. a statement that the refund is being made pursuant to this CIA;
- 2. a description of the complete circumstances surrounding the overpayment;
- 3. the methodology by which the overpayment was determined;
- 4. the amount of the overpayment;
- 5. any claim-specific information used to determine the overpayment (e.g., beneficiary health insurance number, claim number, service date, and payment date);
- 6. the cost reporting period; and
- 7. the provider identification number under which the repayment is being made.

If VillaView determines that there is a material deficiency, contemporaneous with VillaView's notification to the payor as provided above (if there is an overpayment), VillaView shall also notify OIG of:

- 1. a complete description of the material deficiency;
- 2. amount of overpayment due to the material deficiency (if applicable);
- 3. VillaView's action(s) to correct and prevent such material deficiency from recurring;
- 4. the payor's name, address, and contact person where the overpayment was sent (if applicable); and,
- 5. the date of the check and identification number (or electronic transaction number) on which the overpayment was repaid (if applicable).

For purposes of this CIA, an "overpayment" shall mean the amount of money the provider has received in excess of the amount due and payable under the Federal health care programs' statutes, regulations or program directives, including carrier and intermediary instructions.

For purposes of this CIA, a "material deficiency" shall mean anything that involves: (i) a substantial overpayment or improper payment relating to the Medicare and/or Medicaid programs; (ii) conduct or policies that clearly violate the Medicare and/or Medicaid statute, regulations or directives issued by HCFA and/or its agents; or (iii) serious quality of care implications for Federal health care beneficiaries or recipients. A material deficiency may be the result of an isolated event or a series of occurrences.

IV. <u>New Locations</u>

In the event that ViewView purchases or establishes new business units after the effective date of this CIA, VillaView shall notify OIG of this fact within thirty (30) days of the date of purchase or establishment. This notification shall include the location of the new operation(s), phone number, fax number, Federal health care program provider number(s) (if any), and the corresponding payor(s) (contractor specific) that has issued each provider number. All employees at such locations shall be subject to the requirements in this CIA that apply to new employees (e.g., completing certifications and undergoing training).

V. IMPLEMENTATION AND ANNUAL REPORTS

A. <u>Implementation Report</u>. Within one hundred and fifty (150) days after the effective date of this CIA, VillaView shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA. This Implementation Report shall include:

- 1. the name, address, phone number and position description of the Compliance Officer required by section III.A;
- 2. the names and positions of the members of the Compliance Committee required by section III.A;
- 3. a copy of VillaView's Code of Conduct required by section III.B.1;
- 4. the summary of the Policies and Procedures required by section III.B.2;

- 5. a description of the training programs required by section III.C including a description of the targeted audiences and a schedule of when the training sessions were held;
- 6. a certification by the Compliance Officer that:
 - a. the Policies and Procedures required by section III.B have been developed, are being implemented, and have been distributed to all pertinent employees, contractors, and agents;
 - b. all employees, contractors, and agents have completed the Code of Conduct certification required by section III.B.1; and
 - c. all employees, contractors, and agents have completed the training and executed the certification required by section III.C.
- 7. a description of the confidential disclosure program required by section III.E;
- 8. the identity of the Independent Review Organization(s) and the proposed start and completion date of the first review; and
- 9. a summary of personnel actions taken pursuant to section III.F.
- B. Annual Reports. VillaView shall submit to OIG an Annual Report with respect to the status and findings of VillaView's compliance activities. The Annual Reports shall include:
 - 1. any change in the identity or position description of the Compliance Officer and/or members of the Compliance Committee described in section III.A;
 - 2. a certification by the Compliance Officer that:
 - a. all employees, contractors, and agents have completed the annual Code of Conduct certification required by section III.B.1; and
 - b. all employees, contractors, and agents have completed the training and executed the certification required by section III.C;

- 3. notification of any changes or amendments to the Policies and Procedures required by section III.B and the reasons for such changes (e.g., change in contractor policy);
- 4. a complete copy of the report prepared pursuant to the Independent Review Organization's billing and compliance engagement, including a copy of the methodology used;
- 5. VillaView's response/corrective action plan to any issues raised by the Independent Review Organization;
- 6. a summary of material deficiencies reported throughout the course of the previous twelve (12) months pursuant to III.H and the results of any corrective action plans that were instituted;
- 7. a report of the aggregate overpayments that have been returned to the Federal health care programs that were discovered as a direct or indirect result of implementing this CIA. Overpayment amounts should be broken down into the following categories: Medicare, Medicaid (report each applicable state separately) and other Federal health care programs;
- 8. a copy of the confidential disclosure log required by section III.E;
- 9. a description of any personnel action (other than hiring) taken by VillaView as a result of the obligations in section III.F;
- 10. a summary describing any ongoing investigation or legal proceeding conducted or brought by a governmental entity involving an allegation that VillaView, its employees, or agents, have committed a crime or have engaged in fraudulent activities, which have been reported pursuant to section III.G. The statement shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation, legal proceeding or requests for information; and,
- 11. a listing of all of the VillaView's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Federal health care program provider identification number(s) and the payor (specific contractor) that issued each provider identification number.

The first Annual Report shall be received by the OIG no later than one year and thirty (30) days after the effective date of this CIA. Subsequent Annual Reports shall be submitted no later than the anniversary date of the due date of the first Annual Report.

C. <u>Certifications</u>. The Implementation Report and Annual Reports shall include a certification by the Compliance Officer under penalty of perjury, that: (1) VillaView is in compliance with all of the requirements of this CIA, to the best of his or her knowledge; and (2) the Compliance Officer has reviewed the Report and has made reasonable inquiry regarding its content and believes that, upon such inquiry, the information is accurate and truthful.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing subsequent to the effective date of this CIA, all notifications and reports required under this CIA shall be submitted to the entities listed below:

OIG:

Civil Recoveries Branch - Compliance Unit Office of Counsel to the Inspector General Office of Inspector General U.S. Department of Health and Human Services Cohen Building, Room 5527 330 Independence Avenue, SW Washington, DC 20201 Phone 202.619.2078 Fax 202.205.0604

VillaView:

Compliance Officer
VillaView Community Hospital
5550 University Avenue
San Diego, California 92105-0127
Phone 619.582.3516 ext. 3430
Fax 619.265.1784

VII. OIG INSPECTION, AUDIT AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s), may examine VillaView's books, records, and other documents and supporting materials for the purpose of verifying and evaluating: (a) VillaView's compliance with the terms of this CIA; and (b) VillaView's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by VillaView to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of VillaView's employees, contractors, or agents who consent to be interviewed at the employee's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the employee, contractor or agent and OIG. VillaView agrees to assist OIG in contacting and arranging interviews with such employees, contractors or agents upon OIG's request. VillaView's employees, contractors, or agents may elect to be interviewed with or without a representative of VillaView present.

VIII. DOCUMENT AND RECORD RETENTION

VillaView shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs or to compliance with this CIA, one year longer than the term of this CIA (or longer if otherwise required by law).

IX. DISCLOSURES

Subject to HHS's Freedom of Information Act ("FOIA") procedures, set forth in 45 C.F.R. Part 5, the OIG shall make a reasonable effort to notify VillaView prior to any release by OIG of information submitted by VillaView pursuant to its obligations under this CIA and identified upon submission by VillaView as trade secrets, commercial or financial information and privileged and confidential under the FOIA rules. VillaView shall refrain from identifying any information as trade secrets, commercial or financial information and privileged and confidential that does not meet the criteria for exemption from disclosure under FOIA.

X. Breach and Default Provisions

VillaView is expected to fully and timely comply with all of the obligations herein throughout the term of this CIA or other time frames herein agreed to.

- A. <u>Stipulated Penalties for Failure to Comply with Certain Obligations</u>. As a contractual remedy, VillaView and OIG hereby agree that failure to comply with certain obligations set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.
- 1. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day, beginning the day after time frame specified in this CIA, and concluding at the end of the term of this CIA, VillaView fails to have in place any of the following:
 - a. a Compliance Officer;
 - b. a Compliance Committee;
 - c. written Code of Conduct;
 - d. written Policies and Procedures;
 - e. a training program; or
 - f. a Confidential Disclosure Program;
- 2. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day VillaView fails meet any of the deadlines to submit the Implementation Report or the Annual Reports to the OIG.
- 3. A Stipulated Penalty of \$2,000 (which shall begin to accrue on the date the failure to comply began) for each day VillaView:
- a. hires or enters into a contract with or grants staff privileges to an Ineligible Person after that person has been listed by a federal agency as excluded, debarred, suspended or otherwise ineligible for participation in the Medicare, Medicaid or any other Federal health care program (as defined in 42 U.S.C. § 1320a-7b(f)) (this Stipulated Penalty shall not be demanded for any time period during which Villa View can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.F) as to the status of the person);
- b. employs or contracts with or grants staff privileges to an Ineligible Person and that person: (i) has responsibility for, or involvement with, Villa

View's business operations related to the Federal health care programs or (ii) is in a position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds (this Stipulated Penalty shall not be demanded for any time period during which Villa View can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.F) as to the status of the person); or

- c. employs or contracts with a person who: (i) has been charged with a criminal offense related to any Federal health care program, or (ii) is suspended or proposed for exclusion, and that person has responsibility for, or involvement with, Villa View's business operations related to the Federal health care programs (this Stipulated Penalty shall not be demanded for any time period before 10 days after Villa View received notice of the relevant matter or after the resolution of the matter).
- 4. A Stipulated Penalty of \$1,500 (which shall begin to accrue on the date the VillaView fails to grant access) for each day VillaView fails to grant access to the information or documentation as required in section VII of this CIA.
- 5. A Stipulated Penalty of \$1,000 (which shall begin to accrue ten (10) days after the date that OIG provides notice to VillaView of the failure to comply) for each day VillaView fails to comply fully and adequately with any obligation of this CIA. In its notice to VillaView, the OIG shall state the specific grounds for its determination that the VillaView has failed to comply fully and adequately with the CIA obligation(s) at issue.

B. Payment of Stipulated Penalties.

1. Demand Letter. Upon a finding that VillaView has failed to comply with any of the obligations described in section X.A and determining that Stipulated Penalties are appropriate, OIG shall notify VillaView by personal service or certified mail of (a) VillaView's failure to comply; and (b) the OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter").

Within fifteen (15) days of the date of the Demand Letter, VillaView shall either (a) cure the breach to the OIG's satisfaction and pay the applicable stipulated penalties; or (b) request a hearing before an HHS administrative law judge ("ALJ") to dispute the OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in section X.D. In the event VillaView elects to request an ALJ hearing, the

Stipulated Penalties shall continue to accrue until VillaView cures, to the OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under section X.C.

- 2. Timely Written Requests for Extensions. VillaView may submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after VillaView fails to meet the revised deadline as agreed to by the OIG-approved extension. Notwithstanding any other provision in this section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until two (2) business days after VillaView receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five (5) business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.
- 3. Form of Payment. Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in section VI.
- 4. Independence from Material Breach Determination. Except as otherwise noted, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for the OIG's determination that VillaView has materially breached this CIA, which decision shall be made at the OIG's discretion and governed by the provisions in section X.C, below.

C. Exclusion for Material Breach of this CIA

1. Notice of Material Breach and Intent to Exclude. The parties agree that a material breach of this CIA by VillaView constitutes an independent basis for VillaView's exclusion from participation in the Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)). Upon a determination by OIG that VillaView has materially breached this CIA and that exclusion should be imposed, the OIG shall notify VillaView by certified mail of: (a) VillaView's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

- 2. Opportunity to Cure. VillaView shall have thirty five (35) days from the date of the Notice of Material Breach and Intent to Exclude Letter to demonstrate to the OIG's satisfaction that:
 - a. VillaView is in full compliance with this CIA;
 - b. the alleged material breach has been cured; or
 - c. the alleged material breach cannot be cured within the thirty five (35) day period, but that: (i) VillaView has begun to take action to cure the material breach; (ii) VillaView is pursuing such action with due diligence; and (iii) VillaView has provided to OIG a reasonable timetable for curing the material breach.
- 3. Exclusion Letter. If at the conclusion of the thirty five (35) day period, VillaView fails to satisfy the requirements of section X.C.2, OIG may exclude VillaView from participation in the Federal health care programs. OIG will notify VillaView in writing of its determination to exclude VillaView (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in section X.D, below, the exclusion shall go into effect thirty (30) days after the date of the Exclusion Letter. The exclusion shall have national effect and will also apply to all other Federal procurement and non-procurement programs. If VillaView is excluded under the provisions of this CIA, VillaView may seek reinstatement pursuant to the provisions at 42 C.F.R. §§ 1001.3001-.3004.
 - 4. Material Breach. A material breach of this CIA means:
 - a. a failure by VillaView to report a material deficiency, take corrective action and pay the appropriate refunds, as provided in section III.H;
 - b. repeated or flagrant violations of the obligations under this CIA, including, but not limited to, the obligations addressed in section X.A of this CIA:
 - c. a failure to respond to a Demand letter concerning the payment of Stipulated Penalties in accordance with section X.B above; or

d. a failure to retain and use an Independent Review Organization for review purposes in accordance with section III.D.

D. Dispute Resolution

- 1. Review Rights. Upon the OIG's delivery to VillaView of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under the obligation of this CIA, VillaView shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. § 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, the OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an ALJ and, in the event of an appeal, the Departmental Appeals Board ("DAB"), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving stipulated penalties shall be made within fifteen (15) days of the date of the Demand Letter and the request for a hearing involving exclusion shall be made within thirty (30) days of the date of the Exclusion Letter.
- 2. Stipulated Penalties Review. Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for stipulated penalties under this CIA shall be (a) whether VillaView was in full and timely compliance with the obligations of this CIA for which the OIG demands payment; and (b) the period of noncompliance. VillaView shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. If the ALJ finds for the OIG with regard to a finding of a breach of this CIA and orders VillaView to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable twenty (20) days after the ALJ issues such a decision notwithstanding that VillaView may request review of the ALJ decision by the DAB.
- 3. Exclusion Review. Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be (a) whether VillaView was in material breach of this CIA; (b) whether such breach was continuing on the date of the Exclusion Letter; and (c) the alleged material breach cannot be cured within the 35 day period, but that: (i) VillaView has begun to take action to cure the material breach, (ii) VillaView is pursuing such action with due diligence, and (iii) VillaView has provided to OIG a reasonable timetable for curing the material breach.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision that is favorable to the OIG. VillaView's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude VillaView upon the issuance of the ALJ's decision. If the ALJ sustains the determination of the OIG and determines that exclusion is authorized, such exclusion shall take effect twenty (20) days after the ALJ issues such a decision, notwithstanding that VillaView may request review of the ALJ decision by the DAB.

4. Finality of Decision. The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA and VillaView agrees to waive any right it may have to appeal the decision administratively, judicially or otherwise seek review by any court or other adjudicative forum.

XI. EFFECTIVE AND BINDING AGREEMENT

Consistent with the provisions in the Settlement Agreement pursuant to which this CIA is entered, and into which this CIA is incorporated, VillaView and OIG agree as follows:

- A. This CIA shall be binding on the successors, assigns and transferees of VillaView, including, but not limited to, any transaction where the provider number is maintained;
- B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;
- C. Any modifications to this CIA shall be made with the prior written consent of the parties to this CIA; and
- D. The undersigned VillaView signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.

ON BEHALF OF VILLAVIEW COMMUNITY HOSPITAL

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Chairman, Board of Directors

2/24/99 DATE

Mary K. Norvell, Esq.

Counsel for VillaView Community Hospital

Foley & Lardner

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ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

LEWIS MORRIS

Assistant Inspector General for Legal Affairs

Office of Inspector General

U. S. Department of Health and Human Services

3/12/9